K131754

510(k) SUMMARY

JUL 3 1 2013

1. Date: July 28, 2013

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4. Device Name: Wondfo Cocaine Urine Test (COC100)
Wondfo Cannabinoids Urine Test (THC40)

Classification:

Product Code	CFR #	Panel
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoid Test System	Toxicology

5. Predicate Devices:
K050394
Medtox Diagnostics Sure-Screen

6. Intended Use
Wondfo Cocaine Urine Test (COC 100) is an immunochromatographic assay for the qualitative determination of Benzoylecgonine in human urine at a Cut-Off concentration of 100 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.
The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Wondfo Cannabinoids Urine Test (THC 40) is an immunochromatographic assay for the qualitative determination of 11-nor-Δ9-THC-9-COOH in human urine at a Cut-Off concentration of 40 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.
The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred

confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

7. Device Description

Immunochromatograph assays for Cocaine and Cannabinoids Urine Tests use a lateral flow, one step system for the qualitative detection of Benzoylecgonine and 11-nor-Δ9-THC-9-COOH (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes.

8. Substantial Equivalence Information

A summary comparison of features of the Wondfo Cocaine Urine Test (COC 100) and Wondfo Cannabinoids Urine Test (THC 40) and the predicate devices is provided in Table 1 & Table 2.

Table 1: Features Comparison of Wondfo Cocaine Urine Test (COC 100) and the Predicate Devices

Item	Device	Predicate - K050394
Indication(s) for Use	For the qualitative determination of Benzoylecgonine in human urine. For prescription use.	Same (but the number of drugs detected is different)
Calibrator	Benzoylecgonine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	100 ng/mL	Same
Configurations	Cup, Dip Card	Cup

Table 2: Features Comparison of Wondfo Cannabinoids Urine Test (THC 40) and the Predicate Devices

Item	Device	Predicate - K050394
Indication(s) for Use	For the qualitative determination of 11-nor-Δ9-THC-9-COOH in human urine.	Same (but the number of drugs detected is different)
Calibrator	11-nor-Δ9-THC-9-COOH	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody	Same

Item	Device	Predicate - K050394
	immunochemistry.	
Type of Test	Qualitative to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut-Off Values	40 ng/mL	Same
Configurations	Cup, Dip Card	Cup

9. Test Principle

It is a rapid test for the qualitative detection of Benzoylecgonine and 11-nor-Δ9-THC-9-COOH in urine samples. It is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentration below the target cut off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cutoff, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in the test region, indicating a potentially positive result.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off , +75% cut off and +100%cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blinded labeled by the person who prepared the samples and that person did not take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following table.

Cup Format

COC 100:

Result / COC 100	-100% Cut-Off	-75% Cut-Off	-50% Cut-Off	-25% Cut-Off	Cut-Off	+25% Cut-Off	+50% Cut-Off	+75% Cut-Off	+100% Cut-Off
LOT W1070901CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1070902CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1070903CU2	50-/0+	50-/0+	50-/0+	50-/0+	47+/3-	50+/0-	50+/0-	50+/0-	50+/0-

THC 40:

Result / THC 40	-100% Cut-Off	-75% Cut-Off	-50% Cut-Off	-25% Cut-Off	Cut-Off	+25% Cut-Off	+50% Cut-Off	+75% Cut-Off	+100% Cut-Off
LOT W1970901CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1970902CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

Result / THC 40	-100% Cut-Off	-75% Cut-Off	-50% Cut-Off	-25% Cut-Off	Cut-Off	+25% Cut-Off	+50% Cut-Off	+75% Cut-Off	+100% Cut-Off
LOT W1970903CU2	50-/0+	50-/0+	50-/0+	50-/0+	47+/3-	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

COC 100:

Result / COC 100	-100% Cut-Off	-75% Cut-Off	-50% Cut-Off	-25% Cut-Off	Cut-Off	+25% Cut-Off	+50% Cut-Off	+75% Cut-Off	+100% Cut-Off
LOT W1070901P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1070902P	50-/0+	50-/0+	50-/0+	50-/0+	47+/3-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1070903P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

THC 40:

Result / THC 40	-100% Cut-Off	-75% Cut-Off	-50% Cut-Off	-25% Cut-Off	Cut-Off	+25% Cut-Off	+50% Cut-Off	+75% Cut-Off	+100% Cut-Off
LOT W1970901P	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1970902P	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1970903P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable

c. Stability

Stable at 4-30°C for 18 months based on the accelerated stability study at 50°C and real time stability determination at both 4°C and 30°C.

d. Cut-off

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for both cocaine and cannabinoids. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Wondfo Cocaine Urine Test (COC 100)	Benzoylecgonine	100
Wondfo Cannabinoids Urine Test (THC 40)	11-nor-Δ9-THC-9-COOH	40

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentration at 25% below and 25% above Cut-Off level respectively. These urine samples were tested using three batches of each device for both Dip Card and Cup formats.

Compounds that show no interference at a concentration of 100 μg/mL are summarized in the following tables. There are no differences observed for both Dip Card and Cup formats.

COC 100

Acetominophen	Estrone-3-sulfate	Papaverine
Acetophenetidin	Ethyl-p-aminobenzoate	Penicillin-G
N-Acetylprocainamide	Fenoprofen	Pentobarbital
Acetylsalicylic acid	Furosemide	Perphenazine
Aminopyrine	Gentisic acid	Phencyclidine
Amitryptyline	Hemoglobin	Phenelzine

Amobarbital	Hydralazine	Phenobarbital
Amoxicillin	Hydrochlorothiazide	Phentermine
Ampicillin	Hydrocodone	L-Phenylephrine
L-Ascorbic acid	Hydrocortisone	β-Phenylethylamine
DL-Amphetamine Sulfate	O-Hydroxyhippuric acid	Phenylpropanolamine
Apomorphine	p-Hydroxymethamphetamine	Prednisolone
Aspartame	3-Hydroxytyramine	Prednisone
Atropine	Ibuprofen	Procaine
Benzilic acid	Imipramine	Promazine
Benzoic acid	Iproniazid	Promethazine
Benzphetamine	(±) - Isoproterenol	DL-Propranolol
Bilirubin	Isoxsuprine	D-Propoxyphene
(±) -Brompheniramine	Ketamine	D-Pseudoephedrine
Caffeine	Ketoprofen	Quinidine
Cannabidiol	Labetalol	Quinine
Cannabinol	Levorphanol	Ranitidine
Chloralhydrate	Loperamide	Salicylic acid
Chloramphenicol	Maprotiline	Secobarbital
Chlordiazepoxide	Meperidine	Serotonin
Chlorothiazide	Meprobamate	Sulfamethazine
(±) -Chlorpheniramine	Methadone	Sulindac
Chlorpromazine	Methoxyphenamine	Temazepam
Chlorquine	(±)-3,4-Methylene dioxyamphetamine	Tetracycline
Cholesterol	hydrochloride(±)-3,4-Methylene-dioxymethamphetamine hydrochloride	Tetrahydrocortisone, 3-Acetate
Clomipramine	Morphine-3-β-D glucuronide	Tetrahydrocortisone 3-(β-D glucuronide)
Clonidine	Morphine Sulfate	Tetrahydrozoline
Codeine	Nalidixic acid	Thebaine
Cortisone	Naloxone	Thiamine
(-) Cotinine	Naltrexone	Thioridazine
Creatinine	Naproxen	DL-Tyrosine
Deoxycorticosterone	Niacinamide	Tolbutamide
Dextromethorphan	Nifedipine	Triamterene
Diazepam	Norcodein	Trifluoperazine
Diclofenac	Norethindrone	Trimethoprim
Diflunisal	D-Norpropoxyphene	Trimipramine
Digoxin	Noscapine	Tryptamine
Diphenhydramine	DL-Octopamine	DL-Tryptophan
Doxylamine	Oxalic acid	Tyramine
Ecgonine methylester	Oxazepam	Uric acid
(-) - Ψ-Ephedrine	Oxolinic acid	Verapamil

Erythromycin	Oxycodone	Zomepirac
β-Estradiol	Oxymetazoline	

THC 40

4-Acetamidophenol	Estrone-3-sulfate	Penicillin-G
Acetophenetidin	Ethyl-p-aminobenzoate	Pentazocine
N-Acetylprocainamide	Fenoprofen	Pentobarbital
Acetylsalicylic acid	Furosemide	Perphenazine
Aminopyrine	Gentisic acid	Phencyclidine
Amitryptyline	Hemoglobin	Phenelzine
Amobarbital	Hydralazine	Phenobarbital
Amoxicillin	Hydrochlorothiazide	Phentermine
Ampicillin	Hydrocodone	L-Phenylephrine
Ascorbic acid	Hydrocortisone	β-Phenylethlamine
D,L-Amphetamine	O-Hydroxyhippuric acid	β-Phenyllethylamine
L-Amphetamine	3-Hydroxytyramine	Phenylpropanolamine
Apomorphine	Ibuprofen	Prednisolone
Aspartame	Imipramine	Prednisone
Atropine	Iproniazid	Procaine
Benzilic acid	(-) Isoproterenol	Promazine
Benzoic acid	Isoxsuprine	Promethazine
Benzoylecgonine	Ketamine	D,L-Propanolol
Benzphetamine	Ketoprofen	D-Propoxyphene
Bilirubin	Labetalol	D-Pseudoephedrine
Brompheniramine	Levorphanol	Quinidine
Caffeine	Loperamide	Quinine
Chloralhydrate	Maprotiline	Ranitidine
Chloramphenicol	Meprobamate	Salicylic acid
Chlordiazepoxide	Methadone	Secobarbital
Chlorothiazide	Methoxyphenamine	Serotonin (5-Hydroxytyramine)
(±) Chlorpheniramine	(+)3,4-Methylenedioxyamphetamine	Sulfamethazine
Chlorpromazine	(+)3,4-Methylenedioxymethampheta mine	Sulindac
Chlorquine	Methylphenidate	Temazepam
Cholesterol	Methyprylon	Tetracycline
Clomipramine	Morphine-3-β-Dglucuronide	Tetrahydrocortisone, 3 Acetate
Clonidine	Nalorphine	Tetrahydrocortisone3 (5-Dglucuronide)
Cocaine hydrochloride	Naloxone	Tetrahydrozoline
Codeine	Nalidixic acid	Thebaine
Cortisone	Naltrexone	Thiamine
(-) Cotinine	Naproxen	Thioridazine
Creatinine	Niacinamide	D, L-Thyroxine
Deoxycorticosterone	Nifedipine	Tolbutamine

Dextromethorphan	Norcodein	Triamterene
Diazepam	Norethindrone	Trifluoperazine
Diclofenac	D-Norpropoxyphene	Trimethoprim
Diflunisal	Noscapine	Trimipramine
Digoxin	D,L-Octopamine	Tryptamine
Diphenhydramine	Oxalic acid	D, L-Tryptophan
Doxylamine	Oxazepam	Tyramine
Ecgonine hydrochloride	Oxolinic acid	PrD, L-Tyrosine
Ecgonine methylester	Oxycodone	Uric acid
(-) Y Ephedrine	Oxymetazoline	Verapamil
Erythromycin	p-Hydroxymethamphetamine	Zomepirac
β-Estradiol	Papaverine	

f. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for both Dip Card and Cup formats. Compounds that produced positive results are listed below. There are no differences observed for both Dip Card and Cup formats.

COC 100

COC(Cocaine) (Benzoylecgonine, Cut-off=100 ng/mL)	**Minimum Concentration Required to Obtain a Positive Result (ng/mL)**	**% Cross-Reactivity**
Benzoylecgonine	100	100%
Cocaine HCl	250	40.0%
Cocaethylene	4000	2.5%
Ecgonine	10000	1%

THC 40

THC(11-nor-Δ9-THC-9-COOH) (11-nor-Δ9-THC-9-COOH, Cut-off=40 ng/mL)	**Minimum Concentration Required to Obtain a Positive Result (ng/mL)**	**% Cross-Reactivity**
11-nor-Δ9-THC-9-COOH	40	100%
11-nor-Δ8-THC-9-COOH	20	200%
11-hydroxy-Δ9-Tetrahydrocannabinol	2000	2%
Δ 8-Tetrahydrocannabinol	6000	<1%
Δ 9-Tetrahydrocannabinol	8000	<1%
Cannabinol	80000	<1%
Cannabidiol	80000	<1%

g. Effect of Urine Specified Gravity and Urine pH

To investigate the effect of urine specified gravity and urine pH, the urine samples, with 1.000~1.035 specified gravity or urine samples with pH 4~9 were spiked with target drugs at 25% below and 25% above Cut-Off level, respectively. These samples

were tested using three batches of each device for both Dip Card and Cup formats. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed for both Dip Card and Cup formats.

2. Comparison Studies

The method comparison for the Wondfo Cocaine Urine Test (COC100), Wondfo Cannabinoids Urine Test (THC40) was performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the table below:

COC 100:

Cup Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-Off Negative by GC/MS (Between -50% and Cut-Off)	Near Cut-Off Positive by GC/MS (Between the Cut-Off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	Positive	0	0	2	27	13
	Negative	10	15	13	0	0
Viewer B	Positive	0	0	2	27	13
	Negative	10	15	13	0	0
Viewer C	Positive	0	0	1	27	13
	Negative	10	15	14	0	0

Dip Card Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-Off Negative by GC/MS (Between -50% and Cut-Off)	Near Cut-Off Positive by GC/MS (Between the Cut-Off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	Positive	0	0	2	27	13
	Negative	10	15	13	0	0
Viewer B	Positive	0	0	3	27	13
	Negative	10	15	12	0	0
Viewer C	Positive	0	0	2	27	13
	Negative	10	15	13	0	0

Discordant Results of COC 100

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer A	COC1063	90	Positive
Viewer A	COC1065	99	Positive
Viewer B	COC1065	99	Positive
Viewer B	COC1217	86	Positive

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer C	COC1063	90	Positive

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	COC1065	99	Positive
Viewer A	COC1217	86	Positive
Viewer B	COC1063	90	Positive
Viewer B	COC1065	99	Positive
Viewer B	COC1217	86	Positive
Viewer C	COC1031	78	Positive
Viewer C	COC1063	90	Positive

THC 40:

Cup Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-Off Negative by GC/MS (Between -50% and Cut-Off)	Near Cut-Off Positive by GC/MS (Between the Cut-Off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	Positive	0	0	2	20	20
	Negative	10	13	15	0	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	13	16	0	0
Viewer C	Positive	0	0	2	20	20
	Negative	10	13	15	0	0

Dip Card Format

Wondfo Result		Drug-free	Low Negative by GC/MS (Less than -50%)	Near Cut-Off Negative by GC/MS (Between -50% and Cut-Off)	Near Cut-Off Positive by GC/MS (Between the Cut-Off and +50%)	High Positive by GC/MS (Greater than +50%)
Viewer A	Positive	0	0	2	20	20
	Negative	10	13	15	0	0
Viewer B	Positive	0	0	2	20	20
	Negative	10	13	15	0	0
Viewer C	Positive	0	0	3	20	20
	Negative	10	13	14	0	0

Discordant Results of THC 40

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer A	THC4033	33	Positive

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer A	THC4217	36	Positive
Viewer B	THC4033	33	Positive
Viewer C	THC4032	33	Positive
Viewer C	THC4217	36	Positive

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	THC4032	33	Positive
Viewer A	THC4217	36	Positive
Viewer B	THC4032	33	Positive
Viewer B	THC4033	33	Positive
Viewer C	THC4032	33	Positive
Viewer C	THC4033	33	Positive
Viewer C	THC4217	36	Positive

3. Clinical Studies

   Not applicable

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that Wondfo Cocaine Urine Test (COC 100), and Wondfo Cannabinoids Urine Test (THC 40) are substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 31, 2013

Guangzhou Wondfo Biotech Co., Ltd.
C/O Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
GAITHERSBURG MD 20878

Re: K131754
Trade/Device Name: Wondfo Cocaine Urine Test (COC100)
Wondfo Cannabinoids Urine Test (THC40)
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: II
Product Code: DIO, LDJ
Dated: July 2, 2013
Received: July 8, 2013

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131754

Device Name: Wondfo Cocaine Urine Test (COC 100)
Wondfo Cannabinoids Urine Test (THC 40)

Indications for Use:

Wondfo Cocaine Urine Test (COC 100)

Wondfo Cocaine Urine Test (COC 100) is an immunochromatographic assay for the qualitative determination of Benzoylecgonine in human urine at a Cut-Off concentration of 100 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
2013.07.31 08:07:53 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131754

Indications for Use

510(k) Number (if known): k131754

Device Name: Wondfo Cocaine Urine Test (COC 100)
Wondfo Cannabinoids Urine Test (THC 40)

Indications for Use:

Wondfo Cannabinoids Urine Test (THC 40)

Wondfo Cannabinoids Urine Test (THC 40) is an immunochromatographic assay for the qualitative determination of 11-nor-Δ9-THC-9-COOH in human urine at a Cut-Off concentration of 40 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use __X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Denise Johnson-Iyles -S
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